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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/517,908   | 01/30/2006  | Akio Wakabayashi     | 09-278-US                       | 6878             |
| 20306 7590 05/03/2010<br>MCDONNELL BOEHNNEN HULBERT & BERGHOFF LLP<br>300 S. WACKER DRIVE<br>32ND FLOOR<br>CHICAGO, IL 60606 |             |                      | EXAMINER<br>ANDERSON, MICHAEL J |                  |
|  |             |                      | ART UNIT                        | PAPER NUMBER     |
|  |             |                      | 3767                            |                  |
|  |             |                      | MAIL DATE                       | DELIVERY MODE    |
|  |             |                      | 05/03/2010 PAPER                |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/517,908

**Applicant(s)**

WAKABAYASHI, AKIO

**Examiner**

MICHAEL J. ANDERSON

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-43 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Ash (US 5,002,054).

With regards to claim 32, Ash discloses (figures 1-11) a system for efficient drainage of the chest area in the region of the heart, comprising: a source of vacuum (21) at very high negative pressure greater than about 300 torr (column 8, lines 42-66); and a small caliber drainage tubing (11', 16) having a **generally** closed distal end (figure 1b, the loop is **generally** closed to all constituents larger than the selected pore sizes) and a connection to said source of vacuum downstream from said distal end, said drainage tubing having a plurality of holes of an effective size and shape selected to ensure a suction force communicated within the chest cavity to remove fluid but which is maintained insufficient to damage the tissues exposed in the chest area in the vicinity of said drainage tubing (column 7, lines 40-47).

With regards to claim 33, Ash discloses (figures 1-11, as for claim 32 above) a system for reducing cardiac tamponade by providing highly efficient drainage of the chest area in the region of the heart, comprising: a source of

vacuum at very high negative pressure greater than about 300 torr (column 8, lines 42-66); and a drainage tubing having a generally closed distal end and a connection to said source of vacuum downstream from said distal end, said drainage tubing having a plurality of holes of an effective size and shape selected to ensure a suction force communicated within the chest cavity to remove fluid but which is maintained insufficient to damage the tissues exposed in the chest area in the vicinity of said drainage tubing (column 7, lines 40-47).

With regards to claim 34, Ash discloses (figures 1-11, as for claim 32 above) a highly efficient drainage device for draining fluid from a body cavity, such as the chest, comprising: a tube having a generally closed distal end and another end for connection with a source of very high negative pressure, said tube having a plurality of holes having an area greater than that of a circle with an area around one half of an internal diameter of the tube, said internal diameter of said tube being chosen to ensure a suction force communicated within the body cavity to remove fluid but which is maintained insufficient to damage the tissues exposed in the vicinity of said drainage tubing.

With regards to claim 35, Ash discloses (figures 1-11, as for claim 32 above) the drainage device of claim 34 wherein said negative pressure is at least about 125 torr.

With regards to claim 36, Ash discloses (figures 1-11, as for claim 32 above) a drainage device for draining a body cavity, comprising: a tube having a first and a second end, said first end adapted to be inserted into the body cavity and being effectively closed, and a tube wall, a plurality of holes formed into said

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tube wall in an area of said tube that is intended to be inserted into the chest area, a second end of said tube being adapted for receiving a source of vacuum, said source of vacuum being at a level of at least 300mm Hg, said holes being of a size and quantity such that a suction force from any of said holes is insufficient to cause any significant injury to body tissue proximate a hole, while efficiently draining fluid from body cavity (column 7, lines 40-47).

With regards to claim 37, Ash discloses (figures 1-11, as for claim 32 above) the drainage device of claim 36 wherein said tube is of a small caliber, and wherein a largest hole is approximately circular in diameter with an effective diameter no greater than about one half of an internal diameter of said tube in the region of said holes.

With regards to claim 38, Ash discloses (figures 1-11, as for claim 32 above) the drainage device of claim 37 wherein said effective diameter is about 1mm (abstract, column 7, lines 40-47).

With regards to claim 39, Ash discloses (figures 1-11, as for claim 32 above) the drainage device of claim 37 wherein said effective diameter is about 0.5mm (abstract, column 7, lines 40-47).

With regards to claim 40, Ash discloses (figures 1-11, as for claim 32 above) the drainage device of claim 36 wherein said hole size and vacuum level yield a force of about 0.4N at a hole (column 7, lines 40-47 and column 8, lines 42-67).

With regards to claim 41, Ash discloses (figures 1-11, as for claim 32 above) a system for efficient drainage of a body cavity, comprising: a source of

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vacuum at very high pressure; and a small caliber drainage tubing having a generally closed distal end and a connection to said source of vacuum downstream from said distal end, said drainage tubing having a plurality of holes of an effective size and shape selected to ensure a suction force communicated within the body cavity to remove fluid but which is maintained insufficient to damage the tissues exposed in the vicinity of said drainage tubing, wherein said hole size and number are selected to yield a force of about 0.4N at a hole (column 7, lines 40-47 and column 8, lines 42-67).

With regards to claim 42, Ash discloses (figures 1-11, as for claim 32 above) the drainage system of claim 41 wherein said body cavity is the chest area in the region of the heart (column 7, 17-22).

With regards to claim 43, Ash discloses (figures 1-11, as for claim 32 above) a system for efficient drainage of a body cavity, comprising: a source of vacuum at very high pressure; and a small caliber drainage tubing having a generally closed distal end and a connection to said source of vacuum downstream from said distal end, said drainage tubing having a plurality of holes of an effective size and shape selected to ensure a suction force communicated within the body cavity to remove fluid but which is maintained insufficient to damage the tissues exposed in the vicinity of said drainage tubing, wherein said hole size and number are selected to yield a force of about that of capillary blood pressure (column 7, lines 24-39).

With regards to claim 43, Ash discloses (figures 1-11, as for claim 32 above) the drainage device of claim 36 wherein said hole size and vacuum level

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yield a force in the range of about 0.2N to 0.8N at a hole (Ash provides for this limitation, column 7, lines 40-47 and column 8, lines 42-67).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash.

With regards to claims 44 and 45, Ash discloses (figures 1-11, as for claim 32 above) a drainage device of claim 36. However Ash does not explicitly disclose wherein a diameter of the tube is in the range of 4 F to 15 F or 13 F. Ash discloses the claimed invention except for tube size. It would have been an obvious matter of design choice to use a 13 F tube, since such a modification

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would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Ash discloses the use different tube diameters and pores sizes (column 7, lines 40-47 and column 8, lines 42-67). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tube size of Ash as suggested by Ash for filtering different size matter.

### ***Response to Amendment***

The present communication responds to the Amendment of 7/30/2009. By this communication, claims 1-31 are all canceled and new claims 32-46 were added. The amendments did not add new matter. Claims 32-46 are pending. The rejection(s) are as stated.

### ***Response to Arguments***

Applicant's arguments filed 32-46 have been fully considered but they are not persuasive. With regards to applicants' arguments concerning independent claims 32, 33, 34, 36, 41 and 43 and dependent claims 44-45 not having a generally closed distal end it is noted that Ash discloses (figure 1b) a tube with loop at the distal end which is generally closed except to substances smaller than the predetermined pore size (abstract). With regards to applicants' arguments concerning dependent claims 38 and 39, it is noted that Ash (column 7, lines 40-47), discloses an example for the maximum size of the pores to filter cells, etc.



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Furthermore, Ash discloses (column 10, lines 28-38) that larger pore sizes (with magnitudes on the order of 100 microns), reduce the problem of blood clots compared to smaller pore sizes. It is noted that pore sizes with magnitudes on the order of 100 microns or 0.1mm to 0.9mm overlap the required limitation range of **about 0.5mm and about 1mm**.

In response to applicant's argument that Ash discloses a filtration and collection device and not a drainage device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/  
Examiner  
Art Unit 3767

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MJA

4/30/2010

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767